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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124067
Facility ID: 117119
Inspection ID #117119009

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-15

February 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Melvin S. Rapelyea, M.D.
Breast Health Center
Howard County General Hospital
5755 Cedar Lane
Columbia, Maryland 21044

Dear Dr. Rapelyea:

A representative from the State of Maryland under contract to the Food and Drug Administration (FDA) inspected your facility on January 26, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following repeated Level 2 finding:

- [redacted] **Radiologist, did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a repeated Level 2 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- **Radiologic Technologist [redacted] did not meet the continuing education requirement of having completed a minimum of 15 Continuing Education Units in mammography in a 36-month period (1 CEU in 36 months).**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott MacIntire, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District